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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,475	12/03/2001	Akinori Arimura	0032-0264P	3377

2292 7590 12/30/2003

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EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/30/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/980,475**

Applicant(s)  
**Arimura et al.**

Examiner  
**Deepak Rao**

Art Unit  
**1624**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 9, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 11, 12, 14-16, 18, 20, and 24 ☒ are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 7, 11, 12, 14-16, and 24 ☒ are allowed.
- 6) ☒ Claim(s) 1-4, 18, and 20 ☒ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other:

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### **DETAILED ACTION**

This office action is in response to the amendment filed on October 9, 2003.

Claims 1-4, 6-7, 11-12, 14-16, 18, 20 and 24 are pending in this application.

***The following rejections are withdrawn:***

1. The rejections under 35 U.S.C. 112, first and second paragraph of the previous office action are hereby withdrawn in view of the amendments and/or remarks.
2. The rejection under 35 U.S.C. 101 of the previous office action is hereby withdrawn in view of the amendments.
3. The rejection under 35 U.S.C. 102(a) of the previous office action is hereby withdrawn. Applicant filed the English translation of the foreign priority papers and accordingly, Tanimoto et al., WO 99/38829 is not available as a reference.
4. The terminal disclaimer filed on October 9, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,562,817 has been reviewed and is accepted. The terminal disclaimer has been recorded. The obviousness-type double patenting rejection is withdrawn in view of the terminal disclaimer.

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*The following rejections are under new grounds:*

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Henle et al., U.S. patent No. 5,693,611. The reference discloses [1,1'-biphenyl]-4yl-3-pyridinyl compounds that are useful as pharmaceutical agents in the treatment of skin infections, see the structural formula I in col. 1, compound of Example 6D and the activity of the compounds in col. 39 starting at line 34. The instant claims 1-4 include 'a method of treating dermatitis, etc.' and therefore, read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claim 20 is evident from the specification page 53. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed diseases and therefore, the instantly claimed mechanism of 'inhibiting Th0 cells to Th2 cells' is inherently taught in the reference.

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2. Claims 1, 3-4, 18 and 20 are rejected as being anticipated by Lowe et al., WO 98/24766. The reference discloses [1,1'-biphenyl]-4-yl-2-pyridinyl compounds that are useful in pharmaceutical agents in the treatment of asthma, ulcerative colitis, rheumatoid arthritis, see the structural formula (I) in page 1, compounds of Examples 1, 2, etc. and the pharmaceutical activity of the compounds in page 4 starting at line 29. The instant claims 1, 3-4 include 'a method of treating ulcerative colitis, etc.' and therefore, read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claim 20 is evident from the specification page 53. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed diseases and therefore, the instantly claimed mechanism of 'inhibiting Th0 cells to Th2 cells' is inherently taught in the reference.

***Allowable Subject Matter***

Claims 6-7, 11-12, 14-16 and 24 are allowed. The prior art of record does not teach or fairly suggest the instantly claimed methods of using the compounds.

Receipt is acknowledged of the Information Disclosure Statement filed on October 9, 2003 and a copy is enclosed herewith.


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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

December 29, 2003